Real-world treatment patterns and outcomes of patients with advanced renal cell carcinoma (aRCC) treated with first-line (1L) axitinib + pembrolizumab therapy

First published: 31/07/2024

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000104

EU PAS number

EUPAS1000000104

Study ID

1000000104

DARWIN EU® study

No

Study countries

United States

Study description

This is a cohort study that includes a cross-sectional physician survey and a retrospective, multi-site, oncology community-based, medical chart abstraction of patients with clear cell aRCC treated with 1L axitinib + pembrolizumab therapy. Cardinal Health will recruit physicians to participate in the study through a proprietary network of community oncologists. Primary data will be collected from participating physicians, who will be asked to complete a one-time survey on treatment management approaches for aRCC. Participating physicians will then be asked to complete electronic case report (eCRF) forms for patients meeting the study selection criteria based on their existing medical records. All patient-level data are secondary data that will be collected retrospectively from existing medical records originally collected as part of routine care by participating providers.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

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Institution

Cardinal Health

Contact details

Study institution contact

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Primary lead investigator

Yaa Ababio

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/06/2023

Actual: 01/06/2023

Study start date

Planned: 12/06/2024

Actual: 31/07/2024

Data analysis start date
Planned: 25/09/2024

Actual: 31/07/2024

Date of final study report
Planned: 30/06/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A4061101_NIS_Protocol_V2.0_10Jun2024_R.pdf(995.06 KB)

A4061101_NIS_Protocol_V3.0_5March2025_Redacted.pdf(433.1 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

This is a cohort study that includes a cross-sectional physician survey and a retrospective, multi-site, oncology community-based, medical chart abstraction of patients with clear cell aRCC treated with 1L axitinib + pembrolizumab therapy.

Main study objective:

The primary objective of the study is to describe patient-level treatment patterns and sequences of therapy after initiation of 1L axitinib + pembrolizumab therapy among patients with advanced renal cell carcinoma (aRCC).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

INLYTA

Study drug International non-proprietary name (INN) or common name

AXITINIB

Anatomical Therapeutic Chemical (ATC) code

(L01EK01) axitinib

axitinib

Medical condition to be studied

Renal cell carcinoma stage IV

Population studied

Short description of the study population

Providers from Cardinal Health Oncology Provider Extended Network (OPEN) in the United States (US) will be eligible to participate in the study if they have treated at least 5 aRCC patients in the past year, are able to participate in research monitored/approved by a centralized independent institutional review board (IRB), and agree to participate in data quality assurance (QA)/quality control (QC) procedures. For the retrospective chart abstraction, patients meeting the eligibility criteria will be identified by oncologists in OPEN. These patients will be adults diagnosed with aRCC who initiated axitinib + pembrolizumab as 1L treatment and have at least six months of follow-up data after initiation of index therapy.

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Patients with advanced renal cell carcinoma (aRCC)

Estimated number of subjects

300

Study design details

Setting

Patients meeting the eligibility criteria will be identified by oncologists from the Cardinal Health Oncology Provider Extended Network (OPEN) in the US who are the patients' treating providers or work in the patient's treating practice.

Outcomes

Primary outcomes: Treatment patterns (duration of treatment, rationale for treatment discontinuation, treatments received beyond 1L axi+pembro); treatment management (dose holds, dose modifications, etc.)

Secondary outcomes: Demographic and clinical characteristics; physicians'

perceptions of treatment management approaches for aRCC
Exploratory outcomes: Real-world overall response rate, real-world progression-free survival, real-world overall survival

Data analysis plan

This is a descriptive analysis of physician survey data a patient-level data, and no formal hypotheses are specified a priori. Counts and frequencies will be used to describe dichotomous and categorical variables and measures of central tendency (mean, median) and spread (minimum, maximum, standard deviation [SD], interquartile range [IQR], as appropriate) for continuous variables. The Kaplan-Meier method will be used for time-to-event estimates, accounting for right-censoring. All statistical analyses will be conducted using Statistical Analysis Software (SAS v. 9.4).

Data management

Data sources

Data source(s), other

Primary data on physicians' treatment management approaches will be collected via a one-time physician survey. Retrospective patient data will be abstracted and entered into an electronic case report form by patients' treating physicians or another physician in that patient's treating practice within the oncology network. The source documents are the patient chart/medical record data housed within the electronic health records (EHRs) and accessed by the participating providers.

Data sources (types)

Electronic healthcare records (EHR)

Patient surveys

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No